K014111

VOCO GmbH · P.O.B./Postfach 767 · D-27457 Cuxhaven (Germany)

Anton-Flettner-Straße 1-3
D-27472 Cuxhaven (Germany)

Telefon: (0 47 21) 7 19-0
intl.: +49 (47 21) 7 19-0

Telefax: (0 47 21) 7 19-1 09
intl.: +49 (47 21) 7 19-1 40

Internet: http://www.voco.de
e-mail: info@voco.de

MAR 6 2002

Ihr Zeichen yr. ref.	Ihre Nachricht vom dtd.	Unser Zeichen our ref.	Datum date

510(k) SUMMARY

REBILDA® SC
(76 EBF)

1. Submitter's Name
2. Contact Person For VOCO GmbH
3. Date that 510(k) Summary Was Prepared
4. Name of the Medical Device (Classification / Common / Proprietary)
5. Legally Marketed Devices To Which Substantial Equivalence Is Claimed
6. Description of the Device
7. Intended Use of the Device
8. Technological Comparison Between Subject and Predicate Device
9. Summary of Preclinical Performance Studies and Conclusions From Preclinical Performance Studies

1. SUBMITTER'S NAME
VOCO GmbH Anton-Flettner-Str. 1-3 27472 Cuxhaven GERMANY
Tel: 011-49-47 21 719 0 Fax: 011-49 47 21 719 140

2.	***U.S. REGULATORY CONTACT PERSON FOR VOCO GmbH***
	Evan Dick, Ph.D E.G. Dick & Associates 7527 Westmoreland Avenue St. Louis, MO 63105
	Tel: (314) 721-0112 Fax: (314) 721-7591

3.	***DATE THAT510(k) SUMMARY WAS PREPARED***
	December 13, 2001

4.	***NAME OF THE MEDICAL DEVICE***	
	Classification name	*Material, tooth shade, resin (Dental 76 EBF)*
	Common / usual name	*Self-curing dental restorative material*
	Proprietary name	*Rebilda SC*

5.	***LEGALLY MARKETED DEVICES TO WHICH SUBSTANTIAL EQUIVALENCE IS CLAIMED***
	Luxacore (K982201, Foremost Dental Mfg.)

6. DESCRIPTION OF THE DEVICE

Rebilda SC is a self-curing, highly radiopaque, flowable composite for core build-up. Rebilda SC has excellent mechanical properties. Rebilda SC is available in two shades, light blue and dentine. The light blue shade shows the preparation margins, while the dentin shade is for use under translucent crowns and bridges. High adhesion to tooth substance is achieved by using Rebilda SC in conjunction with the light-curing dentin/enamal bonding agent Solobond Plus.

Rebilda SC corresponds to EN 24049/ISO 4049

7. INTENDED USE OF THE DEVICE

Rebilda SC is intended to be used for core build-up of vital and non-vital teeth.

8. TECHNOLOGICAL COMPARISON BETWEEN SUBJECT AND PREDICATE DEVICES

Rebilda SC and Luxacore (K982201) are both two-component, self-curing, flowable composites. Both products are primarily composed of silicate glass, methacrylate polymers, and curing catalysts. Both products are substantially equivalent with regard to such physical properties as compressive strength, flexural strength, working time, and hardness.

9. SUMMARY OF PRECLINICAL PERFORMANCE STUDIES AND CONCLUSIONS FROM PRECLINICAL PERFORMANCE STUDIES

Rebilda SC is formulated from chemical components that are commonly associated with currently marketed dental composite materials.

The chemistry of Rebilda SC raises no new issues or questions that effect safety, effectiveness, or biocompatibility for dental composite product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2002

Voco GmbH
C/O Dr. Evan Dick
E. G. Dick & Associates
7527 Westmoreland Avenue
Saint Louis, Missouri 63105

Re: K014111
Trade/Device Name: Rebilda SC
Regulation Number: 872.3690
Regulation Name: Tooth Shade, Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 14, 2001
Received: December 14, 2001

Dear Dr. Dick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K014111

Device Name: Rebilda SC

Indications For Use:

Rebilda SC is a self-curing, radiopaque, flowable composite intended to be used for core build-up in vital and non-vital teeth.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ **OR** **Over-The-Counter** _____

(as per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K014111